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EXAMINER
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ART UNIT	PAPER NUMBER
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/567,095	SUZUKI ET AL.	
	Examiner	Art Unit	
	KATHERINE SALMON	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-13 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-13 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 03 February 2006 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 9/10/07;5/25/06.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-13 are pending.

2. An action on the merits for Claims 1-13 is set forth below.

Information Disclosure Statement

3. The information disclosure statements (IDS) submitted on 5/25/2006 and 9/10/2007 have been considered by the examiner.

It is noted that the NPL documents for Kajimoto et al, Kitani et al, Minowa et al, and Kuratsune et al. have been received, however, no translation of the NPL document or a translation of the abstract has been received for any of the NPL documents.

Oath/Declaration

4. The oath filed 6/13/2007 has been received with all the required statements.

Drawings

5. The drawings filed 2/03/2006 are accepted.

Specification

6. The disclosure is objected to because of the following informalities: The term "person" has been misspelled as "parson" on p. 12 lines 4 and 6.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-2 and 4-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-2 and 4-8 are indefinite because the claims do not recite a clear nexus between the preamble of the claim and the process steps of the claims. The preamble of Claim 1 states a method of judging fatigue. The positive active step of Claim 1 is drawn to using a value obtained by quantitatively analyzing an adenine nucleotide. As such there are no positive active steps directed to judging fatigue and the claims are therefore incomplete. The claims are incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are steps of an association of the value obtained by quantitatively analyzing an adenine and judging fatigue. Because these steps are missing there is no positive active step to make a determination of judging fatigue.

Claim Rejections - 35 USC § 112/ Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404,

> "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The breadth of the claims and nature of the invention

Claim 1 is drawn to a method of judging fatigue comprising judging fatigue by using a value obtained by quantitatively analyzing an adenine nucleotide in a sample to be measured. Claim 2 is drawn to associating the analyzed adenine nucleotide with fatigue.

Claim 3 is drawn to a method of analyzing a sample to be measured obtained form a subject for judging fatigue which comprises quantitatively analyzing an adenine

nucleotide in the sample to be measured, and associating the value obtained by quantitative analysis with fatigue.

Claim 4 and 9 are drawn to a method wherein the fatigue is judged by comparing a value obtained quantitatively in the sample with a value from a healthy person. Claim 5 and 10 are drawn to defining the adenine nucleotide. Claim 6 and 11 are drawn to defining the quantitative analysis. Claim 7 and 12 define the sample type. Claim 8 and 13 define the chronic fatigue syndrome.

The claims are drawn to "judging fatigue" however the term can encompass numerous measurements including determining the presence of fatigue, monitoring fatigue, diagnosing fatigue, determining the predisposition to fatigue, determining the type of fatigue, progression of fatigue, absence of fatigue and severity of fatigue. Neither the specification nor the art teaches the predictable association of adenine with the breadth of the term. The clams are drawn to the analysis of any adenine nucleotide; however, the specification does not provide guidance for the association of any value of adenine with fatigue. The claims are drawn to any fatigue; however the art teaches that such associations are unpredictable. The claims are drawn to obtaining a value from any subject, however, the art teaches that adenine levels differ depending on the population and sample type. Claims 1-3, 5-8, and 10-13 are drawn to determination of a value of adenine for correlation to judging fatigue but do not require any comparison. The claims are drawn to any value, including the concentration, construction ratio, concentration ratio and adenylate energy charge of any adenine, however, neither the art not the specification provide guidance to correlate any value of adenine to judging

any fatigue.

Nature of the Invention

The invention is in a class of invention which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1330 (Fed. Cir. 2001).

Guidance in the Specification

The specification asserts that the definition and general idea of fatigue varies (p. 1 lines 12-15). The specification asserts that in general fatigue is a state of showing temporally qualitative or quantitative reduction of physical and mental working abilities which can be seen when a physical or mental load is continuously applied (p. 1 lines 12-15). The specification asserts that fatigue includes chronic fatigue syndrome, muscular fatigue, mental fatigue, immunological fatigue, fatigue accompanied by endocrinological abnormality and thermal fatigue (p. 1 lines 15-18).

The specification asserts that chronic fatigue syndrome (CFS) is a general idea of a disease in which the subject becomes unable to have a healthy social life due to chronic fatigued feeling of unknown cause as one syndrome for the purpose of revealing its cause of disease and morbid state (p. 1 lines 19-23).

Therefore the term "fatigue" and "CFS" appear to be relative terms which have not been clearly defined in the art or the specification. There is no guidance with regard to the level, concentration, or amount of adenine which is correlative to "judging fatigue".

The claims are drawn to "judging fatigue" however the term can encompass numerous measurements including the presence of fatigue, monitoring fatigue, diagnosing fatigue, determining the predisposition to fatigue, determining the type of fatigue, progression of fatigue, absence of fatigue and severity of fatigue. The instant specification has not provided guidance for the breadth of the claims. The instant specification has not provided any guidance or examples to correlate any adenine to any of these types of measurements.

The instant specification asserts that the adenine detection includes AMP, ADP, ATP, cyclic AMP, and the like (p. 7 lines 9-11). The claims are broadly drawn to the quantification of any adenine. Adenine (Adenine www.chem.duke.edu) is a chemical structure which is found not only in ATP, ADP, and AMP, but in all DNA and RNA (p. 1). Therefore adenine includes the quantification of any adenine structures. This would include the quantification of all DNA, RNA< ATP, AMP, or ADP in any cell of the body. The instant specification has not provided guidance for the breadth of the claims. The skilled artisan would have to perform undue experimentations to determine if there was any association in any adenine with any fatigue. The instant specification has provided no examples with the breadth of the claims. For example, there is no guidance in the art or the specification that DNA or RNA (e.g. components which comprise adenine) concentration is related to fatigue or even changes based upon rather the subject has fatigue.

The specification asserts that with regard to Wong et al. (Chest December 1992 VOl. 102 p. 1716) teaches a load was added to muscles in patients of CFS and healthy

persons a difference was found between partial muscle tissues in terms of a change at the ATP level (p. 4 lines 16-20). The specification assets that although it may be useful as an index of CFS it is difficult to judge fatigue at the individual level synthetically (p. 4 lines 20-25). Although Wong et al. asserts that CFS patients at exhaustion have a relatively reduced intercellular concentration of ATP than controls (abstract), this teaching is not sufficient for the breadth of the claims. Wong et al. teaches that there was a significant different in ATP values during peak exertion, however, there was no different in ATP levels at rest (Table 2 p. 1718). Therefore Wong et al. teaches that depending on the exertion of the tissue ATP levels differ and that at rest there is no correlation between ATP levels and CFS. Further although Wong et al. is asserting a correlation of ATP at peak exertion, this correlation is still not sufficient for support of a scope of enablement because other art (e.g. Barnes et al. discussion below) teaches that such associations were unpredictable.

The instant specification asserts that sample to be measured includes various body fluids such as saliva, urine, blood, sweat, tears, and various tissues such as organ tissues (p. 6 lines 18-22). However the art (see discussion of Edstrom et al) teaches that different tissue types have different ADP/ATP levels. Therefore depending on the sample tested a different value of adenine would be observed. Herein in the instant claims there is no comparisons of the value to any control relative to the sample type used.

The instant specification asserts the value obtained by quantitatively analyzing adenine nucleotides includes concentration of respective adenine nucleotides,

concentration of total adenine nucleotides, concentration ratio of respective adenine nucleotides, construction ration of respective adenine nucleotides and adenylate energy charge (p. 7 lines 16-20). However each of these values provide different values and associations of adenine. The instant specification has not provided guidance as how to correlate any of these measurements to "judging fatigue". For example, the specification has not provided any guidance as to the association of the concentration of total adenine nucleotides to determination of the type of fatigue. For example there is no guidance to determine which concentration of adenine is associated with the severity of fatigue. Further, the specification has not provided guidance as to which adenine nucleotides should be measured. As stated above each cell of the body have components each with adenine nucleotides and there is no guidance for the association of any of these nucleotides to fatigue.

Although the instant specification provides formulas for the determination of the concentration of total adenine nucleotides, concentration ratio of respective adenine nucleotides, construction ratio, and AEC (p. 7 lines 21-23, p. 8 lines 1-13), this calculation is not sufficient to provide support for the claims. The specification has not provided guidance of how the skilled artisan uses the values obtained by these calculation to judge fatigue.

Working Examples

The specification asserts that body fluid or blood was collected form healthy persons and CFS patients (p. 12 lines 6-8). The specification asserts that adenine

nucleotide factional determination was made for ATP measurement, ATP +AMP measurement and ATP+ADP+AMP measurement (p. 12 lines 9-11).

The specification asserts that the results are shown in Figure 1 (p. 13 line 15). Figure 1 shows the relative amount of each Adenine nucleotide measurement, however, does not provide any correlation of fatigue to any of these measurements.

The specification asserts that blood was taken and AMP, ADP, ATP, and total adenine was measure with results in Figure 2-5 (p. 14-p. 15 lines 1-14). The specification asserts that total adenine nucleotide concentration is ATP +ADP +AMP (p. 15 lines 13-14).

Figures 2-5 present AMP, ADP, ATP and total adenine levels for healthy persons and patients. Each of these figures provide a different measurement: concentration ($x10^{-4}$ M figure 2), concentration ($x10^{-7}$ M figure 3), ratio (figure 3), and concentration ($x10^{-17}$ mol/cell Figure 5). Depending on the measurement there are different statistical correlations. In figures 2, and 5, ADP, ATP, and total adenine are statistically significant. In figure 3 only AMP is statistically significant. In Figure 4, only AMP and ATP are statistically significant.

Therefore the instant specification discloses that depending on the type of measurement and the type of adenine, different associations are determined. For instance if the skilled artisan measured the ratio in healthy person and patients with regard to ADP, there would be no correlation between adenine and CFS. Therefore the instant specification has not provided predictable guidance for the breadth of the claims.

Further the significant correlations observed in CFS patients disclosed in the specification are not sufficient to provide enabling support for a scope of the claims, because the art still shows unpredictability within a specific fatigue and adenine type. Wong et al. (as discussed above) teaches that there is no correlation in ATP levels and CFS when the patients were at rest (table 2). Herein in the instant specification there is no guidance as to rather the ATP levels were measured during exertion or at rest. Further, as discussed below, Barnes et al. teaches that there was no consistent abnormalities in CFS patients with regard to ATP or ADP (abstract and p. 680 Table 1). Therefore, although the instant specification might have provided data to a particular fatigue type and adenine value, the art teaches that these values are unpredictable. As such the skilled artisan would have to perform undue experimentation to determine the association of adenine and fatigue.

The unpredictability of the art and the state of the prior art

Barnes et al. (J. Neurol Neurosurg Psychiatry 1993 Vol. 56 p. 679) teaches that there is no consistent abnormalities of mitochondrial metabolism in chronic fatigue (CFS) patients (abstract). Barnes et al. teaches that metabolic ratios were calculated in patients with CFS (p. 679 last paragraph). Table 1 includes an analysis of both ATP and ADP. Table 1 indicates that there were no significant differences between patients with CFS and controls (e.g. patients without CFS) for any of the ratios (p. 680 Table 1). Therefore Barnes concludes that there are no specific metabolic abnormalities (including ATP and ADP levels) in skeletal muscle of patients with CFS (p. 682 2nd

column 2nd full paragraph). In the instant case, there is unpredictability with regard to associating a value of adenine with judging fatigue. Barnes et al. teaches that in the analysis of both ATP and ADP there is no association to CFS.

Davis et al. (Am J Physiol Regulatory Integrative Comp Physiol 2003 Vol. 284 p. 399) teaches that adenosine is a normal cellular constituent that is regulated mainly by ATP metabolism and other adenine nucleotides (p. 399 last paragraph). Davis et al. teaches that adenosine concentration increase in muscle and plasma during muscular contraction (p. 399 last paragraph). Adenosine concentrations also increase progressively in the brain during wakefulness and then decrease during sleep (p. 399 last paragraph). Davis et al. teaches that adenosine concentration are mainly regulated by ATP metabolism (p. 402 2nd column 3rd paragraph). Davis et al. teaches increased breakdown of ATP induces an increase in adenosine concentration (p. 402 2nd column 3rd paragraph). Davis et al. teaches with muscular contraction, adenosine concentrations are raised in the working muscle and in the blood (p. 402 2nd column 3rd paragraph). Davis et al. teaches that brain adenosine increases during wakefulness and various hypoxic/ischemic conditions (p. 402 2nd column 3rd paragraph). Therefore Davis et al. teaches that ATP levels (e.g. adenine nucleotides) are effects by numerous biological factors including muscular contraction, wakefulness and various hypoxic/ischemic conditions. The instant specification has not provided guidance to determine if the different in the adenine levels of a subject are based upon some association with fatigue or with any of the other numerous biological factors.

Edstrom et al. (J. Physiol 1982 Vol 332 p. 47) teaches that high energy phosphates at rest have been measured in skeletal muscles with different fiber type composition from rat, guinea pig, and man (point 1 of summary). Edstrom et al. teaches that fast twitch muscles had a higher ATP/ADP ratio than slow twitch muscles (point 2 of summary). Edstrom et al. teaches that in guinea pig and rat the muscles representing different combination of fast type II muscles had higher ATP/ADP ratios than the slowly contracting soleus muscles (p. 54 last full paragraph). Edstrom et al. teaches that therefore the ATP/ADP ratio is higher in fast twitch muscles than the more slowly contracting muscles (p. 55 1st full paragraph). Therefore Edstrom et al. teaches that depending on the sample, ATP/ADP ratios differ. Therefore a value obtained from a fast type II muscle would be a different value than a value obtained from soleus muscles.

Giannesini et al. (Journal of Physiology 2001 Vol. 536 p. 905) teaches an investigation to determine if a reduction in ATP cost of contraction was related to fatigue level in rat (point 1 abstract). Giannesini et al. teaches that reduction in ATP cost of contraction during stimulation of rat gastrocnemius muscle is not related to fatigue level (point 5 of abstract). Figure 4 c, shows that there was no difference between non-fatiguing and fatiguing with regard to ATP cost of contraction. Giannesini et al. teaches that ATP cost of contraction was reduced throughout non-fatiguing and fatiguing muscles and therefore ATP cost of contraction is not related to the fatigue level (p. 913 last paragraph). Therefore Giannesini et al. teaches that not all values of ATP are associated with judging fatigue.

Coyle (UK Patent Application GB2293449A publication 3/27/1996) teaches a method of using body phosphate stores to monitor or diagnosis fatigue related illness such as myalgic encephalomyelitis or post viral fatigue syndrome (abstract). Coyle et al. teaches phosphate is typically AMP, ADP, or ATP and can be measured by an enzyme based assay (abstract). Coyle et al. teaches myalgic encephalomyelitis or post viral fatigue syndrome are common terms to chronic fatigue syndrome (p. 1 lines 11). However, Coyle et al. does not provide any statistically significant data to equate measurement of an adenine to the diagnosis of phosphate. In table 1, Coyle et al. measures phosphate levels in 10 patients with chronic fatigue syndrome and 10 controls. Coyle et al. teaches that phosphate measurement is a measurement of AMP, ADP or ATP (p. 5 lines 5-8). However, Coyle et al. does not provide any statistically significant data that the phosphate concentration is different in patients with chronic fatigue syndrome and controls. Table 1 provides the phosphate concentration in chronic fatigue syndrome patients (PO4) and controls (C immediately following PO4). These levels do not appear to be significantly different in many of the patients. For example in patient A6 the measurement was 1.03, whereas in the control it was 1.00 and in patient Z8 the measurement was 0/73 whereas the control was 0.80. Coyle et al does not describe which levels of change in the concentration reflect a high degree of change. Therefore, even though at the time of filing the method steps have been described (e.g. Coyle et al.), this description does not provide guidance to the skilled artisan to use the method as broadly claimed. Further based upon the unpredictability

in the art and the lack of guidance in the specification, the skilled artisan would not be able to make or use the claimed method without undue experimentation.

Level of Skill in the Art

The level of skill in the art is deemed to be high.

Quantity of Experimentation and Conclusion

The quantity of experimentation in this area would be extremely large since there is significant number of parameters that would have to be studied. To practice the invention as broadly as it is claimed, the skilled artisan would have to determine every possible value of any adenine in any sample. The skilled artisan would have to associate the value of any adenine with any judgment of fatigue. The skilled artisan would have to make an assessment of fatigue without any comparison step of the value of adenine. Therefore to use the invention as presented would require a large amount of inventive effort, with each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

The skilled artisan would have to perform undue experimentation, which would require an extremely large amount of trial and error analysis in a large study to determine the association of the value of any adenine with any judgment of fatigue. The instant specification does not provide guidance to make or use the method as broadly claimed. Although the instant specification provides an example of a specific type of fatigue (e.g. CFS) and specific measurement of adenine, this is not sufficient for enablement purposes. The working example in the instant specification clearly shows that depending on the measurement used and the adenine type measured there are different associations with the specific fatigue type of CFS.

Further the art teaches that there is still a significant amount of unpredictability. Wong et al. teaches that ATP is only associated with CFS at exertion points and not when the subject is at rest. Barnes et al. teaches that there is no association of ATP and ADP with CFS. Davis et al. teaches that other biological factors influence the level of ATP. Edstrom et al. teaches that ratios of ATP/ADP levels differ depending on sample type. Giannesini et al. teaches that ATP is not related to fatigue level. Therefore the art teaches that there is a large amount of unpredictability to the claimed association.
Therefore even though the specification provides a specific working example of a specific type of fatigue and specific adenine nucleotide, the guidance in the specification weighed against the teachings in the art is not sufficient for enabling support. Both Wong et al. and Barnes et al. teaches that there is unpredictability with the correlation of ATP or ADP levels and chronic fatigue. Further Davis et al, Edstrom et al., and Giannesini et al. teach that adenine levels are effected by numerous biological factors and by sample type. Therefore the art teaches that there is a large amount of unpredictability in associating adenine nucleotides to fatigue.

Therefore the method as claimed would require a large amount of inventive effort, with each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps. Thus given the broad claims in an art whose nature is identified as unpredictable, the unpredictability of that art, the large quantity of research required to define these unpredictable variables, the negative teachings in the art, and the lack of guidance provided in the specification balanced only against the high skill level in the art, it is the position of the examiner that

it would require undue experimentation for one of skill in the art to perform the method of the claim as broadly written.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. In order to have compact prosecution both a 35 USC 102 and a 35 USC 112/Enablement rejection has been made. While Coyle et al. and Wong et al. teach all the method steps as recited in Claims 1-13, as discussed in the 35 USC 112 enablement rejection it does not provide enabling disclosure for these claims. However, the 35 USC 102 rejection is set forth below because Coyle et al. and Wong et al. are enabling to the same extent as the instant specification. Therefore if the specification is found to be enabling the prior art is enabling and therefore the 35 USC 102 will be maintained. However if the specification is found not to be enabling the prior art provides no additional support for enablement.

10. Claims 1-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Coyle (UK Patent Application GB2293449A publication 3/27/1996).

With regard to Claim 1, Coyle et al. teaches a method of measuring AMP, ADP, or ATP to monitor fatigue related illness (abstract), and therefore Coyle et al. teaches a method of judging fatigue by using a value obtained by quantitatively analyzing an adenine nucleotide (e.g. AMP, ADP, or ATP).

With regard to Claim 2, Coyle et al. teaches measuring phosphate concentration to monitor fatigue (p. 4 lines 12-15). Coyle et al. teaches the measurement of phosphate concentration provides a determination of ATP, ADP, and AMP levels (p. 5 lines 5-8). Therefore, Coyle et al. teaches a method of quantitatively analyzing an adenine nucleotide associated with fatigue.

With regard to Claim 3, Coyle et al. teaches analyzing heparinsed blood from an individual (p. 10 lines 24-25), Coyle et al. teaches measuring ATP, ADP, and AMP (p. 11 lines 20-22) and correlating this value to a measurement of fatigue (p. 11 lines 25). Therefore Coyle et al. teaches analyzing a sample obtained from a subject by measuring quantitatively an adenine nucleotide and associating the value with fatigue.

With regard to Claim 4, Coyle et al. teaches measuring phosphate concentration to monitor fatigue (p. 4 lines 12-15). Coyle et al. teaches the measurement of phosphate concentration provides a determination of ATP, ADP, and AMP levels (p. 5 lines 5-8). Coyle et al. teaches comparing this value with that of a normal individual or animal (p. 4 lines 20-21).

With regard to Claim 5, Coyle et al. teaches the detection of AMP, ADP, and ATP (abstract).

With regard to Claim 6, Coyle et al. teaches the value is from the phosphate concentration (e.g. a value obtained by concentration) which is an measurement of ATP, ADP, and AMP (p. 5 lines 5-7).

With regard to Claim 7, Coyle et al. teaches analyzing a blood sample (p. 10 lines 24-25).

With regard to Claim 8, Coyle et al. teaches a method of monitoring or diagnosing (e.g. judging) myalgic encephalomyelitis or post viral fatigue syndrome by monitoring phosphate stores which are composed of ATP, ADP, and AMP (abstract, p 5 lines 5-8, and p. 10 lines 24-26 through p. 11 lines 1-23). Coyle et al. teaches that myalgic encephalomyelitis or post viral fatigue syndrome are general terms given to chronic fatigue syndrome (p. 1 lines 11-12).

With regard to Claim 9, Coyle et al. teaches measuring phosphate concentration to monitor fatigue (p. 4 lines 12-15). Coyle et al. teaches the measurement of phosphate concentration provides a determination of ATP, ADP, and AMP levels (p. 5 lines 5-8). Coyle et al. teaches comparing this value with that of a normal individual or animal (p. 4 lines 20-21).

With regard to Claim 10, Coyle et al. teaches the adenine is ATP, ADP, or AMP (p. 5 lines 5-8).

With regard to Claim 11, Coyle et al. teaches the value is from the phosphate concentration (e.g. a value obtained by concentration) which is an measurement of ATP, ADP, and AMP (p. 5 lines 5-7).

With regard to Claim 12, Coyle et al. teaches analyzing a blood sample (p. 10 lines 24-25).

With regard to Claim 13, Coyle et al. teaches a method of monitoring or diagnosing (e.g. judging) myalgic encephalomyelitis or post viral fatigue syndrome by monitoring phosphate stores which are composed of ATP, ADP, and AMP (abstract, p 5 lines 5-8, and p. 10 lines 24-26 through p. 11 lines 1-23). Coyle et al. teaches that myalgic encephalomyelitis or post viral fatigue syndrome are general terms given to chronic fatigue syndrome (p. 1 lines 11-12).

11. Claims 1-6, 8-11 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Wong et al. (Chest December 1992 VOl. 102 p. 1716).

Wong et al. teaches a load was added to muscles of patients of CFS and healthy persons a difference was found between partial muscle tissues in terms of a change at the ATP level (p. 4 lines 16-20). Therefore Wong et al. teaches a method of judging fatigue by obtaining a value of analyzed adenine nucleotide.

With regard to Claim 2, Wong et al. teaches quantitatively analyzing an adenine nucleotide associated with fatigue (Table 2).

With regard to Claim 3, Wong et al. teaches a load was added to muscles of patients of CFS and healthy persons a difference was found between partial muscle tissues in terms of a change at the ATP level (p. 4 lines 16-20). Wong et al. teaches associating the value to fatigue (Table 2).

With regard to Claim 4, Wong et al. teaches a load was added to muscles of patients of CFS and healthy persons a difference was found between partial muscle tissues in terms of a change at the ATP level (p. 4 lines 16-20). Wong et al. teaches associating the value to fatigue (Table 2). Wong et al. teaches comparing the ATP levels to a normal person (e.g. a healthy person) (Table 2).

With regard to Claim 5, Wong et al. teaches that the adenine is ATP (abstract).

With regard to Claim 6, Wong et al. teaches measuring the concentration of ATP (p. 1717 last paragraph and Figure 1).

With regard to Claim 8, Wong et al. teaches that the fatigue was chronic fatigue syndrome (abstract).

. With regard to Claim 9, Wong et al. teaches a load was added to muscles of patients of CFS and healthy persons a difference was found between partial muscle tissues in terms of a change at the ATP level (p. 4 lines 16-20). Wong et al. teaches associating the value to fatigue (Table 2). Wong et al. teaches comparing the ATP levels to a normal person (e.g. a healthy person) (Table 2).

With regard to Claim 10, Wong et al. teaches that the adenine is ATP (abstract).

With regard to Claim 11, Wong et al. teaches measuring the concentration of ATP (p. 1717 last paragraph and Figure 1).

With regard to Claim 13, Wong et al. teaches that the fatigue was chronic fatigue syndrome (abstract).

Conclusion

12. No Claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE SALMON whose telephone number is (571)272-3316. The examiner can normally be reached on Monday-Friday 8AM-530PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Katherine Salmon/
Examiner, Art Unit 1634

/JD Schultz/

Supervisory Patent Examiner, Art Unit 1635